UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: SANOFI-AVENTIS SECURITIES LITIGATION	07-CV-10279 (GBD) CLASS ACTION
This document relates to: ALL ACTIONS	**ECF CASE**

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT

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Defendants sanofi-aventis ("sanofi") and Douglas Greene (collectively, "Defendants"),[1] submit this memorandum of law in support of their motion to dismiss, pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b), the amended complaint (the "Amended Complaint" or "Cplt.") filed by lead plaintiffs City of Edinburgh Council of the Lothian Pension Fund and New England Carpenters Guaranteed Annuity Fund (together, "Plaintiffs").

PRELIMINARY STATEMENT

Every day, the United States Food and Drug Administration (the "FDA") considers New Drug Applications ("NDAs") submitted by pharmaceutical companies that believe their products are safe and effective for addressing some public health need. The FDA has discretion over which of these applications to approve. Sometimes, the FDA will approve an application and the drug can be marketed in the United States. Sometimes, the FDA requests that a drug's sponsor submit new information prior to approval. And sometimes, the FDA does not approve an application. The filing of an NDA does not guarantee its approval. Every pharmaceutical company—and every investor in a pharmaceutical company—knows this.

Plaintiffs, however, seek to convert sanofi's withdrawn application for approval in the United States of a new drug known as rimonabant[2] into a federal securities fraud claim. Plaintiffs assert the following syllogism: (1) sanofi and certain of its executives made statements indicating their belief that certain studies had shown rimonabant to be safe and effective; and (2) the FDA staff later opined to an FDA advisory committee that it believed the data to show a causal link to certain side effects, and the advisory committee ultimately concluded that there

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[1] The other defendants named in the Amended Complaint, Jean-François Dehecq, Gérard Le Fur, Hanspeter Spek, Marc Cluzel and Jean-Claude Leroy (the "Non-U.S. Defendants") had not been served at the time of the stipulated briefing schedule "so-ordered" by this Court on February 13, 2008, see Docket No. 13, and reserve their rights to move or answer within the time permitted by the Federal Rules if they are properly served.

[2] Rimonabant is also known by the proposed U.S. trademark Zimulti ®, and has been approved for sale as Acomplia ® in the European Union and other jurisdictions. Cplt. ¶ 99; Ex. FF at 4.

was not sufficient data to assess the drug's safety profile; therefore (3) sanofi and its executives must have known before the advisory committee meeting that the drug would not be approved.

The business of developing new drug compounds and obtaining regulatory approval for them is, by its very nature, a speculative endeavor. There is no guarantee that any line of research will ultimately produce a marketable drug, and the regulatory assessment of a new drug is subject to scientific debate and the risk of nonapproval.[3] Each year, the FDA receives over one hundred NDAs, all submitted by sponsors who believe their drug to be safe and effective. The FDA may approve some NDAs; many others are not approved. Investors in pharmaceutical companies are, by definition, speculating that the future financial success of drugs in development will exceed the costs of developing those that fail—as some inevitably will—or like rimonabant are approved in some jurisdictions or for some uses, but not others.[4]

Plaintiffs invested in an enterprise with known, disclosed and inherent risks (and large potential upside), but now seek to shift the cost of a failed venture (or, more accurately, a venture that has not initially succeeded as emphatically as hoped) to unsuspecting future shareholders. This is not and should not be the law, and Courts in this District and elsewhere

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[3] Indeed, sanofi told its investors precisely that. Each sanofi press release states that "investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties," noting that "these risks and uncertainties include those discussed and identified in the public filings with the SEC and the AMF made by sanofi-aventis, including those listed under 'Risk Factors' and 'Cautionary Statement Regarding Forward-Looking Statements' in sanofi-aventis' annual report on Form 20-F. . . . " See, e.g., Exs. I, M. Press releases announcing the publication of the RIO studies also included such language, incorporating by reference the Form 20-F risk factors. See Ex. L (announcing RIO-North America publication); Ex. T (announcing RIO-Diabetes publication); sanofi Press Release of November 16, 2005 (announcing RIO-Lipids publication), available at http://www.sanofi-aventis.us/live/us/en/layout.jsp?cnt=1ECBFB20-3729-4130-9FBC-DF6D6E3D6BFF. Indeed, the published RIO studies themelves included significant cautionary language. See infra n.24. In its Forms 20-F, sanofi consistently reminded investors that "[t]here can be no assurance that any of [the compounds under development] will be proven safe or effective, or that they will produce commercially successful products." Exs. E, K, AA. Sanofi also repeatedly warned investors that "[t]he submission of an application to a regulatory authority provides no assurance that the regulatory authority will grant a license to market the product." Id.

[4] In 2005, for example, the FDA reports taking action on 143 priority and standard NDAs and Biologic License Applications (which are analogous to NDAs for biologics, such as vaccines). Of those actions, 80—approximately 56%—were approvals. See CDER 2005 Report to the Nation: Improving Public Health Through Human Drugs, at 14-16, available at http://www.fda.gov/CDER/reports/rtn/2005/rtn2005.htm.

have consistently rejected such claims at the pleading stage. See, e.g., In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36 (2d Cir. 2000); In re Astrazeneca Sec. Litig., No. 05 Civ. 2688 (TPG), 2008 WL 2332325 (S.D.N.Y. June 3, 2008); Borochoff v. Glaxosmithkline PLC, No. 07 Civ. 5574 (LLS), 2008 WL 2073421 (S.D.N.Y. May 9, 2008); In re Pfizer, Inc. Sec. Litig., No. 06 Civ. 14199 (LAK), 2008 WL 540120 (S.D.N.Y. Feb. 28, 2008); In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004); In re Boston Scientific Corp. Sec. Litig., 490 F. Supp. 2d 142, 158 (D. Mass. 2007); In re Alkermes Sec. Litig., No. Civ.A. 03-12091 (RCL), 2005 WL 2848341 (D. Mass. Oct. 6, 2005).

STATEMENT OF FACTS[5]

I. The Drug Approval Process

Under federal law, no drug may be introduced into interstate commerce unless the Secretary of Health and Human Services, or the FDA as its designee, has approved an application filed under the Food, Drug, and Cosmetic Act, and determined, *inter alia*, that there are sufficient tests showing the drug to be safe and effective for use under the conditions prescribed. See 21 U.S.C. § 355(a), (d). The process to receive FDA approval to market a new drug is lengthy and laborious, with no guarantee of success. Researchers must discover the drug, develop it chemically, and then test it pre-clinically (that is, in non-human subjects). Before the drug is tested in humans, the drug sponsor must submit an Investigational New Drug Application to the FDA, which must approve the design of the clinical tests. See FDA, "The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective," FDA Consumer, July-Aug. 2002 available at http://www.fda.gov/Fdac/features/2002/402_drug.html (with revisions made in

[5] For purposes of this motion only, defendants accept the well-pleaded factual allegations of the Amended Complaint as true. See Flores v. S. Peru Copper Corp., 343 F.3d 140, 143 (2d Cir. 2003). On a motion to dismiss, however, the Court is not required to accept conclusions, and may rely on "the full text of 'documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.'" Pfizer, 2008 WL 540120, at *2 (quoting Tellabs, Inc. v. Makor Issues & Rights, Ltd., __ U.S. __, 127 S. Ct. 2499, 2509 (2007)).

September 2005) ("Drug Review Process"); 21 C.F.R. § 312.[6] After the approved studies are completed, a sponsor submits a NDA, formally asking the FDA to approve the new drug for marketing. 21 U.S.C. § 355(b); Drug Review Process. The FDA makes a threshold determination that an NDA is "sufficiently complete to permit a substantive review." See 21 C.F.R. § 314.101. An FDA review team—medical doctors, chemists, and other experts—then evaluates whether the studies the sponsor submitted show that the drug to be safe and effective for its proposed use, see Drug Review Process, and communicates with the sponsor about "scientific, medical, and procedural issues that arise during the review process." See 21 C.F.R. § 314.102; CDER Manual of Procedures and Policies § 6010.5, available at http://www.fda.gov/cder/mapp.htm (MaPP).

Assuming the NDA is not withdrawn and no contrary agreement is reached, the FDA will provide one of three responses within 180 days after the NDA is accepted for filing: an "approval letter," an "approvable letter" or a "not approvable" letter. 21 C.F.R. § 314.100. The FDA will approve the drug for sale if "none of the grounds for denying approval" are found to exist. 21 U.S.C. § 355(c)(1)(A); 21 C.F.R. § 314.105. The FDA will issue a "not approvable" letter if the application may not be approved for any one of a number of reasons, including that there are not "adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed," the test results show the drug to be unsafe, or there is insufficient information about the safety of the drug. 21 C.F.R. § 314.120; 21 C.F.R. § 314.125. Finally, the FDA may issue an "approvable letter" if the application "is basically approvable providing certain issues are resolved" and the FDA "believes that it can approve the application . . . if specific additional information or material is submitted." 21 C.F.R. § 314.110.

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[6] References to exhibits refer to the Declaration of S. Christopher Provenzano In Support Of Defendants' Motion To Dismiss The Amended Complaint, dated June 27, 2008, and submitted herewith.

If the sponsor chooses to resubmit the NDA with all the data requested by the FDA, the FDA will again review it for safety and efficacy. 21 C.F.R. § 314.110(a); MaPP 6020.4R. Throughout, the FDA exercises its own "scientific judgment" in determining whether a particular drug meets the statutory standards for approval. 21 C.F.R. § 314.105(c). The FDA recognizes that "[n]o drug is absolutely safe. . . . 'Safe' in this sense means that the benefits of the drug appear to outweigh the risks." Drug Review Process.

II. The Allegations Of The Complaint

Sanofi began large-scale clinical trials of rimonabant in humans beginning in 2001, and studies continue to the present. See Exs. A-D (RIO studies); HH at 40-41 (Transcript of the June 13, 2007 Advisory Committee ("AC Tr.")); JJ at 5. Between 2001 and 2004, independent scientists conducted clinical studies funded by sanofi, such as the published Rimonabant in Obesity studies ("RIO Studies"), which concluded that a 20 mg dose of rimonabant produced clinically meaningful reductions in weight and waist circumference. See Exs. A-D (RIO studies). On April 28, 2006, after a lengthy regulatory process, rimonabant was recommended for marketing approval in the European Union (under the name "Acomplia ®") by the EMEA,[7] see Ex. P, and, on June 21, 2006, the European Commission granted marketing approval of the drug. See Cplt. ¶ 99, Ex. R. As of June 29, 2007, rimonabant had been approved in 42 countries and was marketed in 20 of them. See sanofi press release of June 29, 2007, available at http://www.sanofi-aventis.us/live/us/medias/07B70509-ED2F-4FCE-9533-EDB7187D57AB.pdf. As of March 26, 2008, the drug had been approved in 56 countries. See

[7] Like the FDA, the Committee for Medicinal Products for Human Use ("CMPH"), as part of the European Medicines Agency ("EMEA"), requires evidence of a drug's safety and efficacy and considers the risk-benefit balance in granting an authorization. See Reg. (EC) No.726/2004 (Art. 12(1) and 14(2)). The CMPH also requires a comprehensive application, including the results of clinical trials. Reg. (EC) No. 726/2004 (Article 6(1)); Directive 2001/83/EC.

March 26, 2008, sanofi press release , available at http://en.sanofi-aventis.com/Images/0803026_ACOMPLIA_NICE_ENG_tcm24-20629.pdf.

In April 2005, sanofi submitted an NDA seeking approval of the drug for a variety of indications, including weight loss and metabolic disorders. Ex. K; Cplt. ¶ 75. On February 17, 2006, the FDA issued an Approvable Letter with respect to rimonabant's obesity indication, meaning the drug was "basically approvable" with issues to be resolved. Cplt. ¶¶ 75, 83; Ex. M. Sanofi completed its resubmission of the NDA on October 26, 2006, and, on December 8, 2006, the FDA deemed sanofi's response to be complete. See Cplt. ¶ 112, Ex. Z. Thereafter, the FDA conducted its scientific and medical evaluation of the NDA, including choosing to convene a meeting—as it has discretion to do—of the Endocrinologic and Metabolic Drugs Advisory Committee. See Cplt. ¶ 118; Ex. DD; 21 C.F.R. §§ 14.160, 14.171.[8]

The advisory committee met publicly on June 13, 2007, and heard presentations from both sanofi and FDA reviewers on rimonabant's safety and efficacy. See Cplt. ¶ 125; Ex. HH. Sanofi presented scientists and medical doctors who opined that the clinical studies showed rimonabant to be beneficial and effective, and did not show a statistically significant relationship between rimonabant and side effects that would preclude approval. See Ex. HH at 114, 122, 168-70. The FDA did not dispute efficacy. See Ex. HH at 12-13. However, its staff presenter on safety opined, on the basis of the same clinical data, that rimonabant was causally related to depression and a new clinical concept called suicidality. See Ex. HH at 291-92. The committee voted that "the currently available data [did not] sufficiently characterize[] rimonabant's safety profile" and that, balancing risks against benefits, it could not conclude that the current data presented "a favorable risk-benefit profile." See Cplt. ¶ 126, Ex. HH at 335, 383-84; see also

[8] The FDA may, but is not required to, convene an advisory committee at any time to offer its views to the FDA on any issues referred to it with respect to a pending NDA. 21 C.F.R. §§ 14.160, 14.171.

Summary Minutes of the Endocrinologic and Metabolic Drugs Advisory Committee meeting on June 13, 2007 ("Summary Minutes"), available at http://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4306m1-final.pdf. Two weeks later, sanofi announced that it would withdraw its NDA and work toward submitting it at a future date. See Cplt. ¶¶ 32,133.

The Amended Complaint purports to assert claims on behalf of U.S.-based purchasers and sellers of sanofi stock on the New York Stock Exchange ("NYSE") or on any foreign exchange, as well as foreign purchasers on the NYSE. In essence, the Amended Complaint alleges that sanofi and each of the individual defendants made statements "touting" the safety of rimonabant during the pendency of the NDA. See Cplt. ¶¶ 24-35. Plaintiffs claim the "truth" about rimonabant was only revealed at the FDA advisory committee meeting. See Cplt. ¶¶ 36-39; cf. Ex. HH (AC Tr.). To support this claim, Plaintiffs point almost entirely to statements made by sanofi and the individual defendants that either (accurately) described the results of the RIO studies or made the point, which the filing of the NDA itself made, that sanofi believed the drug to be safe and effective. As to *scienter*, Plaintiffs point to the conclusions expressed by the FDA staff at the end of the class period. Plaintiffs' allegations as to falsity and *scienter* are patently insufficient under the clear and abundant caselaw in this Circuit and elsewhere; the Amended Complaint should be dismissed with prejudice.

ARGUMENT

I. Legal Standards

The bar for pleading a securities fraud claim is high.[9] Plaintiffs must allege that each defendant: "(1) made misstatements or omissions of material fact; (2) with scienter; (3) in

[9] Plaintiffs also allege "control person" liability under Section 20(a) of the Exchange Act. Because liability under Section 20(a) necessarily depends on a primary violation of the securities laws, the failure of Plaintiffs to state

connection with the purchase or sale of securities; (4) upon which plaintiffs relied; and (5) that plaintiffs' reliance was the proximate cause of their injury." See, e.g., Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 172 (2d Cir. 2005). The Private Securities Litigation Reform Act ("PSLRA") requires that "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). In addition, a complaint alleging securities fraud must, "with respect to each act or omission alleged . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The required state of mind is "'a mental state embracing intent to deceive, manipulate, or defraud.'" Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., No. 06-2902-cv, WL 252 1676, at 9 (2d Cir. June 26, 2008) (quoting Tellabs, 127 S. Ct. at 2504). As the Supreme Court has explained:

> The inference of scienter must be more than merely "reasonable" or "permissible"—it must be cogent and compelling, thus strong in light of other explanations. A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.

Tellabs, 127 S. Ct. at 2510. Federal Rule of Civil Procedure 9(b) also requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."

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a claim under Section 10(b) and Rule 10b-5 is fatal to their Section 20(a) claim. Rombach v. Chang, 355 F.3d 164, 177-78 (2d Cir. 2004); see also In re Astrazeneca Sec. Litig., No. 05 Civ. 2688 (TPG), 2008 WL 2332325, at *18 (S.D.N.Y. June 3, 2008) (group pleading cannot create scienter as to individual defendants).

II. Plaintiffs Fail Sufficiently To Allege Any False Or Misleading Statements

The nub of Plaintiffs' complaint appears to be that during its development of rimonabant, sanofi stated that—if approved for sale by the FDA—the drug would likely be a blockbuster product that would generate "an immediate and long-lasting revenue stream for Sanofi," Cplt. ¶ 6, but "failed to disclose to investors that clinical study data revealed that rimonabant caused suicidal ideation and depression." Cplt. ¶ 5. Plaintiffs do not dispute that rimonabant is effective in treating obesity, a condition that Plaintiffs describe as having "reached epidemic proportions and [as] a major health concern in the United States." Cplt. ¶ 6.[10] Nor do they dispute that rimonabant had "the potential to be a truly gargantuan 'blockbuster' drug" had it been approved by the FDA.[11] Id. Rather, plaintiffs claim that Defendants knowingly concealed a causal relationship between use of rimonabant and suicidality. Cplt. ¶¶ 6, 35. But, Plaintiffs fail to identify any statement that defendants made that was false or misleading.

A. Sanofi's Statements Describing The Rimonabant Studies Are Not False

Plaintiffs' prolix and repetitive complaint is primarily devoted to the claim that sanofi incorrectly summarized the results of the RIO Studies. Plaintiffs complain principally that sanofi or its employees stated in press releases or conferences that:

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[10] Thus statements such as that rimonabant produced "'significant reductions and maintenance in waist circumference and weight improvements,'" Cplt. ¶ 31, are not alleged to have been false. See also Cplt. ¶¶ 68 (same), 79 (rimonabant "held therapeutic promise"), 80 (rimonabant showed "clinically meaningful" benefits), 87 (general discussion of RIO results), 90 (discussing efficacy of rimonabant), 114 (same), 115 (statement about improvements to "cardiometabolic risk factors"), 119 (referring to "reduction in weight and waist circumference").

[11] The advisory committee's vote that more data was required before rimonabant could be approved in the United States did not result in other jurisdictions declining to approve rimonabant or withdrawing the drug from their markets. In fact, following the June 13, 2007 advisory committee meeting, the EMEA concluded "that the benefits of Acomplia continue to outweigh its risks, except in patients with ongoing major depression or taking antidepressants." See EMEA press release of July 19, 2007, Doc. Ref. EMEA/329826/2007, available at http://www.emea.europa.eu/humandocs/PDFs/EPAR/acomplia/32982607en.pdf. More recently, on June 25, the United Kingdom's National Institute for Health and Clinical Excellence ("NICE") issued final guidance recommending rimonabant "as an addition to diet and exercise for adults who are obese or overweight and who have had an inadequate response to, are intolerant of or are contraindicated to orlistat and sibutramine." See NICE press release of June 25, 2008, Ref. No. 2008/037, available at http://www.nice.org.uk/media/BB3/53/2008037Rimonabant.pdf.

(1) The RIO-Europe study showed that "[s]ide effects were mainly mild and transient and appeared mainly in the first year[, consisting of] nausea, dizziness, diarrhea and vomiting" and had "a safety profile which, in the second year, is essentially identical or comparable to what we see in the placebo group." Cplt. ¶¶ 67-68;

(2) The results of RIO-North America "were consistent with other reported RIO studies" and showed that the most common side effects included respiratory tract infection, nasopharyngitis, nausea, influenza, anxiety, and depressed mood, that overall discontinuation rates were significantly higher for rimonabant 20 mg patients than for placebo treated patients, and that "[t]he most common adverse events leading to discontinuation for the placebo and rimonabant 20 mg patients respectively were depressed mood disorder . . . anxiety . . . and nausea." Cplt. ¶ 80; and

(3) The RIO-Diabetes study showed that "[s]ide effects were mainly mild, transient, self-limiting and occurred early in the treatment period" and the most common side effects included nausea, dizziness, diarrhoea, vomiting, self-reported hypoglycaemia, fatigue, and anxiety. Cplt. ¶ 102; see also Cplt. ¶ 74.

In short, sanofi stated, the results of the RIO Studies showed a "discontinuation rate due to adverse reactions [of] 15.7% for patients receiving Acomplia," the "most common adverse events resulting in discontinuation were nausea, mood alteration with depressive disorders, anxiety and dizziness," Cplt. ¶ 99, that "[a]dverse events usually occurred during first months and were generally of mild to moderate intensity," and that during the second year of treatment there was "no increased adverse event reporting or discontinuation rate" and the second-year safety profile "was generally not different from that of placebo or year one." Cplt. ¶ 106.

Plaintiffs, however, fail to allege that any of sanofi's statements were false. First, the results of the RIO Studies themselves were contemporaneously and widely published in respected and peer-reviewed medical journals during the class period.[12] If any material facts were omitted from the releases announcing the studies (and Plaintiffs do not allege there were

[12] RIO-Europe (Ex. A) was published in The Lancet on April 16, 2005; RIO-Lipids (Ex. B) in the New England Journal of Medicine on November 17, 2005; RIO-North America (Ex. C) in the Journal of the American Medical Association on February 15, 2006; and RIO-Diabetes (Ex. D) in The Lancet on November 11, 2006.

any), any investor could simply read the reports published in medical journals, which were available to the market.

Second, sanofi's releases accurately summarized the studies, and Plaintiffs do not allege otherwise.[13] The RIO-Europe study disclosed the side effects and the safety profile described in sanofi's statements, and indicated that rimonabant was in fact "generally well tolerated with mild and transient side effects." Ex. A at 1389; cf. Cplt. ¶¶ 67-68. The RIO-North America study showed results similar to those of the other RIO Studies, including side effects (as sanofi indicated), and found that "[r]imonabant was generally well tolerated" with nausea the most common adverse event. Ex. C at 761; cf. Cplt. ¶ 80. The RIO-Diabetes study found that side effects were mainly mild (as sanofi indicated). Ex. D at 1667; cf. Cplt. ¶ 102. Each of the published RIO Studies generally showed discontinuation rates, side effects, and safety profiles

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[13] Plaintiffs' allegations are too numerous to discuss each in detail. However, a comparison of the published RIO studies with sanofi's statements about them shows that sanofi accurately stated—often in the same words—the findings of the studies. Compare Cplt. ¶ 67 with Ex. A at 1389 (rimonabant well tolerated), 1393-94 (common adverse events described) (note that only the one-year results were published from the RIO-Europe study, but the Plaintiffs have not alleged that the two-year results as presented by Defendants are false); Cplt. ¶ 68 with Ex. A at 1389 (results of study), 1391, Figure 2 and Table 2 (summarizing results), 1396 (favourable safety profile), 1395 (independent effect), 1394 (reported deaths), 1394 (no change in HAD scores), 1390 (clinical practice guidelines); Cplt. ¶¶ 69 and 99 with Ex. A at 1390 (number of patients), Ex. D at 1662 (number of patients), Ex. C at 762 (number of patients), Ex. B at 2124 (number of patients); Cplt ¶ 70 with Ex. C at 773 (first in class drug), 761 (results), Ex. B at 2122 (mode of action); Cplt. ¶¶ 74, 87, 90, and 119 with Ex. A at 1389, 1392 Table 3 (consistency of results), Ex. D at 1660, 1664 Table 2 (consistency of results), Ex. C at 761, 763-64 Tables 1-2 (consistency of results); Ex. B at 2121, 2126, Table 2 and 2128 Figure 1 (consistency of results); Cplt. ¶ 74 with Ex. A at 1393-94 (common adverse events, mild and transient), Ex. B at 2130 (common adverse events), Ex. C at 772, 774 (common adverse events, well tolerated), Ex. D at 1667 (common adverse events, generally mild or moderate), 1667, 1668 Table 4 (serious adverse events); Cplt. ¶ 75 with Ex. C at 774 (innovative approach), 763 (novel strategy for treatment of obesity and cardiometabolic disorders), Ex. D at 1670 (new approach, metabolic risk factors); Cplt. ¶ 79 with Ex. A at 1396 (therapeutic promise), Ex. D at 1667 (results/improvement); Cplt. ¶ 80 with Ex. C at 761 (trial description), 774 (weight loss results), 773 (other results) 772 and 772 Table 4 (adverse events), 773 (withdrawals); Cplt. ¶ 87 with Ex. A at 1390 (number of patients), Ex. D at 1662 (number of patients), Ex. C at 762 (number of patients), Ex. B at 2124 (number of patients); Cplt. ¶ 87 with Ex. C at 774 (comprehensive management), 763 (novel strategy), 773 (first in class), Ex. D at 1670 (new approach, cardiometabolic risks); Cplt. ¶ 90 with Ex. D at 1670 (independent effect); Cplt. ¶ 99 with Ex. A at 1395, Table 7 (discontinuations), Ex. D at 1668 Table 4 (discontinuations), Ex. C at 772 Table 4 (discontinuations), Ex. B at 2131 Table 3 (discontinuations); Cplt. ¶ 99 with Ex. A (RIO-Europe) at 1394 (common adverse events), Ex. D at 1660 (common adverse events), Ex. C at 772-73 (common adverse events), Ex. B at 2130-31 (common adverse events); Cplt. ¶ 102 with Ex. D at 1660 (results/improvement), 1667, 1668 Table 4 (adverse events, safety profile); Cplt. ¶ 106 with Ex. C at 773 (discontinuation rate), 774 (safety profile and exposure), Ex. A at 1393-94 (adverse events).

consistent with what sanofi publicly disclosed. See Exs. A-D. The studies also pointed out their limitations, including that the safety of rimonabant in "patients with severe psychiatric disorders or receiving antidepressants . . . remain[ed] to be determined" (Ex. D at 1670), the difficulties posed by the number of patient drop-outs and the need for further study of the drug's long-term effects. See, e.g., Ex. C at 774; see also infra n.24.

Plaintiffs may be complaining that the studies did not show the causal link between "suicidality" and a 20 mg rimonabant regimen that the FDA staff ultimately opined might be present. However, "[u]nder the PSLRA, . . . 'where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study.'" See Nathenson v. Zonagen Inc., 267 F.3d 400, 419-20 (5th Cir. 2001) (quoting Padnes v. Scios Nova Inc., No. C 95-1693 (MHP), 1996 WL 539711, at *5 (N.D. Cal. Sept. 18, 1996)); see also In re Medimmune, Inc. Sec. Litig., 873 F. Supp. 953, 966 (D. Md. 1995); In re Biogen Sec., 179 F.R.D. 25, 38 (D. Mass. 1997); Pfizer, 2008 WL 540120, at *5. Plaintiffs do not and cannot allege that the RIO Studies even tested for suicidality or suicidal ideation, much less that they reported results regarding suicidality. In fact, the very analysis Plaintiffs rely upon for a causal link between 20 mg rimonabant and suicidality makes clear that there is a "lack of conceptual clarity about suicidal behavior and corresponding lack of well-defined terminology," Ex. II at 3 (Posner presentation), and that the "studies weren't set up to assess for suicidality" Ex HH at 22 (AC Tr.), a notion developed only after the RIO Studies were designed. See infra n.17. And, in each and every release announcing the result of a RIO Study, sanofi reminded investors that regardless of the results of that study, ultimately there could "be no assurance that [rimonabant would] be proven safe or effective." Exs. I, M, E, K, AA; see also supra n.3. See Astrazeneca, 2008 WL 2332325, at *16 (dismissing complaint where drug sponsor "continually

noted that there would need to be an ultimate risk-benefit evaluation, and that it was uncertain what this evaluation would show"). Because plaintiffs fail to allege how or why any of the statements regarding the RIO Studies were false, these claims must be dismissed. See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007) (relying on Fed. R. Civ. P. 9) (internal citations omitted); 15 U.S.C. § 78u-4(b)(1).

The rest of Plaintiffs' allegations rip statements from their context, trying to create the impression that statements that are clearly non-actionable say something they do not say.[14] Plaintiffs suggest Dr. Greene stated as an absolute matter that: "although, there is an increase in the frequency of depressed mood, there is no increase in cases of depression. And, in fact, there is a numerically smaller number of cases of depression in rimonabant 20mg . . . " Cplt. ¶¶ 22, 109. But Dr. Greene was discussing the findings of a single study (SERENADE) and plaintiffs do not allege any respect in which the SERENADE study contradicted those findings. See Ex. X.[15] See also In re Sierra Wireless, Inc. Sec. Litig., 482 F. Supp. 2d 365, 372-

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[14] Plaintiffs allege that although defendant Dr. Cluzel stated that he was sure that more than 2,000 patients had stayed on rimonabant for more than one year, in fact "only approximately 1100 patients completed one year of treatment during the RIO Studies." Cplt. ¶ 27. But the published RIO studies confirm that, as Dr. Cluzel stated, 2925 patients in the RIO studies completed at least one year of rimonabant therapy. See Exs. A-D. This figure does not include those who participated in non-RIO studies. And, the FDA staff confirmed that sanofi's clinical studies complied with then-applicable guidelines. See Ex. HH at 252. In any event, Dr. Cluzel added that he did not know the precise number of patients who completed one year of treatment. See Ex. G at 14.

[15] Moreover, Dr. Greene went on to explain that the distinction between depressed mood and depression was not arbitrary, but was a refinement of the methodology used in the RIO studies:

> Depressed mood is more of an indication of feeling sad, a patient who might say, well, I feel sad or I don't feel happy. Whereas diagnosing it as a case of depression is more of a medical diagnosis in which a physician would assess the fact that the patient is actually depressed. And so we have refined our definitions [from the RIO studies].

See Ex. X. Dr. Greene's truthful statement that "the safety profile was consistent with what we've seen in the past, which we found reassuring" was likewise made in the context of discussing how the data from the SERENADE study compared to the previous RIO studies. Cplt. ¶ 22; cf. Ex. X. The same is true of Dr. Greene's statement that "consistent with the previously demonstrated safety profile, [SERENADE showed] some increase in dizziness, nausea, which is usually mild, self-limited, normally one episode of slight nausea for example." Id. Plaintiffs do not allege that the SERENADE data in any way contradicted Dr. Greene's statements.

73 (S.D.N.Y. 2007); San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 812-13 (2d Cir. 1996).

Likewise, Plaintiffs quote Dr. Cluzel as stating in response to a question about the RIO studies in March 2005: "[o]n suicide *[suicidality]*, in fact, we have no signal." Cplt. ¶¶ 33, 68 (bracketed interpolation in complaint, emphasis added). What Dr. Cluzel stated was that there was no signal on suicide—a true statement. The suicide rate observed in the RIO Studies in fact showed no statistical difference between the placebo and rimonabant groups; hence, there was no "signal."[16] Dr. Cluzel could not have said, and did not say, anything about suicidality for the simple reason that the RIO Studies did not measure suicidality.[17]

The only other statements about safety alleged to be false are statements of opinion or enthusiasm about the results of particular clinical studies. See Cplt. ¶¶ 15, 31, 33-34, 66, 68, 70, 87, 109-10, 114-15, 119. Such statements are simply not actionable: "It is well settled that a complaint alleging violations of the securities laws may not rely upon statements that are true, or constitute puffery or ordinary expressions of corporate optimism. . . . Likewise,

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[16] At the time (in March 2005), there was a single reported incident of possible suicide among patients taking rimonabant in the four completed RIO Studies. See Ex. HH at 116-17. This death was described as a "dea[th] by gunshot" in the RIO-North America study, which also noted that all deaths (including non-suicides) were evenly distributed across all groups, placebo, 5 mg and 20 mg. See Ex. C at 772, Table 4. At the advisory committee, Sanofi discussed deaths across all of the studies that were subsequently classed as suicides in the retrospective analysis performed by Dr. Posner, and noted that the patient who committed suicide while on the 5mg rimonabant regimen had a "past involvement in the Federal Witness Protection Program" and was "pending a very important court decision." Ex. HH at 119.

[17] The RIO studies unambiguously state that they used the HAD scale (for "Hospital Anxiety and Depression"), which does not measure suicidality, to measure depression and similar side effects. See Ex. C at 767, Ex. A at 1391, Ex. B at 2122, and Ex. D at 1661. The document plaintiff relies upon establishes that suicidality is measured by a different test (C-CASA for "Columbia Classification Algorithm for Suicide Assessment") that is a retrospective analytical tool intended to assess previously conducted clinical studies for suicidality, Ex. II at 16 (Posner presentation) Ex. HH at 27-29 (AC Tr.), and that the FDA requested be applied to the clinical data following the success of C-CASA as applied to pediatric trials in September 2004 and after the RIO Studies. Ex. HH at 19; see also the agenda for the September 13-24 FDA Pediatric Advisory Committee, available at http://www.fda.gov/ohrms/dockets/AC/04/agenda/2004-4065A1_Final.htm. At the time of the FDA's request, the RIO studies had already been completed using only the HAD scale. See Ex. C at 761, 767; Ex. A at 1390-91; Ex. B at 2122; and Ex. D at 1660-61.

statements of opinion are insufficient to form the basis of a misrepresentation or omission complaint under § 10(b)." In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004), citing In re Int'l Bus. Machs. Corp. Sec. Litig., 163 F.3d 102, 108 (2d Cir. 1998); Lasker v. N.Y. State Elec. & Gas Corp., 85 F.3d 55, 58-59 (2d Cir. 1996); San Leandro, 75 F.3d at 811. See also Pfizer, 2008 WL 540120, at *5 (finding that "[d]efendants were entitled to take an optimistic view of inconclusive evidence" of a drug's efficacy).

B. Statements Of General Optimism About Rimonabant And "Puffery"

The other statements alleged in the Amended Complaint—for example, that sanofi "remain[ed] confident and prepared to launch Acomplia during the second half of 2006" (Cplt. ¶¶ 17, 32, 96), that sanofi was "extremely optimistic as to obtaining an NDA for Rimonabant" (Cplt. ¶ 114), that rimonabant was "a fantastic product" (Cplt. ¶ 87) and that rimonabant was a "potential blockbuster" (Cplt. ¶ 66)—were either truthful when made or non-actionable statements of optimism.[18] See San Leandro, 75 F.3d at 811; Sierra Wireless, 482 F.Supp.2d at 367 ("[t]he securities laws neither require corporate officers to adopt a crabbed, defeatist view of the company's business prospects nor permit dissatisfied shareholders to assert serious allegations of fraud based on the perfect hindsight afforded by the passage of time"); Pfizer, 2008 WL 540120, at *5 (noting that "corporate officials need not present an overly gloomy or cautious picture" about the potential success of a new drug so long as "public statements are consistent with reasonably available data") (internal citations omitted).

[18] Plaintiffs also allege analyst statements "emphasiz[ed] that '[rimonabant] is en route to mega-blockbuster status' . . . [and] that the compound 'could be one of the most commercially successful drugs in history." Cplt. ¶ 31. For a defendant to be held responsible for a third-party statement, however, the defendant must be deeply involved in the production and control of the statement. See, e.g., Elkind v. Liggett & Myers, Inc., 635 F.2d 156, 163 (2d Cir. 1980), cited in In re ICN/Viratek Sec. Litig., No. 87 Civ. 4296 (KMW), 1996 WL 164732, at *3 (S.D.N.Y. Apr. 9, 1996).

Plaintiffs themselves allege reasons why sanofi was justifiably enthusiastic about the prospects for rimonabant—"100 [million] Americans . . . are considered to suffer from abdominal obesity" (Cplt. ¶ 15)—and rimonabant had demonstrated its efficacy in reducing weight and waist circumference. Moreover, rimonabant had been approved for sale in a large number of other jurisdictions with similarly demanding regulatory regimes. See supra n.11; see also Astrazeneca, 2008 WL 2332325, at *17 (approval in Europe of drug rejected by FDA advisory committee undermined inference of *scienter*). In that context, it would not have been unreasonable (and certainly would not have been fraudulent) for Defendants to comment that projections of "sales of €3.2 billion in 2010 and €4.5 billion in 2015" would not have been "excessive."[19] Cplt. ¶ 72. In Bristol-Myers, a Court in this District held that statements that a drug was "a tremendous strategic opportunity," had "real blockbuster potential," had "the potential to be one of the most exciting, if not the most exciting" cancer drugs, was "a late-stage product with potential to drive the growth of our oncology franchise in the near and medium term and extending into 2018," that it "broaden[ed] [BMS's] growth opportunities through aggressive external development" and was "a first-in-class novel blockbuster drug for treating cancer" were all non-actionable puffery. Bristol Myers, 312 F. Supp. 2d at 557-59 (emphases omitted); see also Astrazeneca, 2008 WL 2332325, at *6 (dismissing complaint where defendant stated market opportunity for a failed drug was "tremendous," and the company "expected to achieve great things" with the drug, which was hoped to keep the business "nicely growing"). If

[19] Plaintiffs cite several other such optimistic statements regarding rimonabant's prospects for commercial success, none of which are actionable. See, e.g., Cplt. ¶¶ 75, 87, 90, 95, 96.

these statements are not sufficient to state a claim, sanofi's far more measured assessments of rimonabant's prospects clearly are not actionable.[20]

Finally, sanofi's truthful discussion of rimonabant's potential did not create a duty to disclose conclusions about scientific evidence that sanofi had not in fact reached. Pfizer, 2008 WL 540120, at *5; see also Borochoff v. Glaxosmithkline PLC, No. 07 Civ. 5574 (LLS), 2008 WL 2073421, at *5 (S.D.N.Y. May 9, 2008) (positive statements about Avandia did not create duty to disclose adverse facts regarding risks); In re Alkermes Sec. Litig., No. Civ.A. 03-12091 (RCL), 2005 WL 2848341, at *16 (D. Mass. Oct. 6, 2005) ("[t]he Defendants had no duty to disclose that the FDA had requested additional studies because they had never guaranteed FDA approval").[21]

III. The Amended Complaint Fails To Allege A Strong Inference Of Scienter

The Amended Complaint suffers from a second fatal defect: it does not satisfy the PSLRA's standards for scienter. "A strong inference of fraudulent intent may be established

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[20] Some of Defendants' allegedly fraudulent statements describe not the rimonabant studies, but truthfully describe the status of rimonabant in the regulatory process, such as: "We know that the products have been received, that they are of course fileable." Cplt. ¶¶ 32, 78. At the time of this statement the rimonabant NDA had, in fact, been deemed fileable and had been accepted for filing with the FDA. See Ex. I. Similarly, the statement that "[n]ew drug applications were filed for rimonabant in the United States and Europe during the second quarter of 2005," Cplt. ¶ 79, is true. See id. Plaintiffs also misleadingly quote only the emphasized portion of the following statement: "You know everything concerning rimonabant. I can just add that we are currently working with the FDA concerning rimonabant, but I'm sorry to say that but you're pretty sure of what I said that will not comment anymore about rimonabant." Cplt. ¶ 33; Ex. O at 6. In context, there is no conceivable way an investor could have understood the statement to mean that investors knew everything about rimonabant that sanofi knew (as opposed to everything that sanofi was prepared to tell investors). At the same time the speaker made the statement, sanofi was declining to provide information about the status of its discussions with the FDA.

[21] Plaintiffs also allege that Defendants failed to disclose the substance of sanofi's discussions with and submissions to the FDA, and in particular, failed to disclose the content of the Approvable Letter. See Cplt. ¶¶ 29, 61, 97(d), 107(d), 116(d), 123(d). However, Plaintiffs offer no specific allegations as to why sanofi or any of the individual defendants was under a specific obligation to disclose this information, and indeed no such duty exists. See, e.g., Oppenheim Pramerica Asset Mgmt. S.A.R.L. v. Encysive Pharms., Inc., No. Civ. A.H. 06-3022 (JA), 2007 WL 2720074, at *3 (S.D. Tex. Sept. 18, 2007) (noting that Defendants' "decision not to discuss publicly the details of the 'approvable' letters did not constitute a material misstatement or omission" and that "[p]laintiffs have not alleged and cannot allege that this decision was unreasonable, given the competitive market conditions"); In re Boston Scientific Corp. Sec. Litig., 490 F. Supp. 2d 142, 158 (D. Mass. 2007) (finding that a major deficiency letter received from the FDA "was a step in the FDA approval process which BSC had no duty to disclose").

either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36, 39 (2d Cir. 2000) (internal citations omitted). Plaintiffs do not come close to satisfying that standard. They do not allege the existence of critical internal reports, undisclosed adverse clinical studies, private stock sales, or indeed any fact with respect to any defendant during the class period that would suggest *scienter*.

Instead, Plaintiffs simply adopt the view expressed by the FDA staff—on the last day of the class period—that the data demonstrated a causal link between a 20 mg regimen of rimonabant and certain psychiatric side effects for which the clinical studies did not even test – and ask the Court to infer that sanofi must have reached that same conclusion during the class period. In fact, the inference of causality was the subject of fierce scientific debate at the advisory committee meeting, defeating any inference of *scienter*. And the advisory committee itself simply voted that "the currently available data [did not] sufficiently characterize[] rimonabant's safety profile," and noted that further data gathering was necessary. Ex. HH at 335, 355, 383-85 (AC Tr.); Summary Minutes. Far from creating an "inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged," see Tellabs, 127 S. Ct. at 2510, Plaintiffs' claims are nothing more than an attempt to plead fraud-by-hindsight and should be dismissed. See, e.g., Pfizer, 2008 WL 540120, at *7 (The "ultimate failure [of an NDA] is not evidence that the side effects were thought to be unmanageable at the time the alleged misstatements were made. Fraud-by-hindsight is not sufficient to establish liability under Rule 10b-5.").

A. Plaintiffs Offer No Allegations That Show Motive To Commit Fraud

Plaintiffs allege that the fact that sanofi had drugs coming off patent and desired to fill its product pipeline created a sufficient motive to infer *scienter*. See Cplt. ¶¶ 8-20. But, every major pharmaceutical company always has drugs coming off patent and a desire to find new blockbusters. These allegations do not establish *scienter*.[22] See Teamsters Local 445, slip op. at 14 ("desire to maintain the appearance of profitability [is] insufficient in securities fraud pleading"); Kalnit v. Eichler, 264 F.3d 131, 139 (2d Cir. 2001) (same). Courts have uniformly dismissed such allegations as insufficient in the pharmaceutical context. See, e.g., id.; Pfizer, 2008 WL 540120, at *7-8 (need for a "blockbuster" insufficient); In re Bayer AG Sec. Litig., No. 03 Civ. 1546 (WHP), 2004 WL 2190357, at *14 (S.D.N.Y. Sept. 30, 2004) ("pressure" to bring "blockbuster" to market insufficient); Bristol-Myers, 312 F. Supp. 2d at 560-61 (concerns about "drug pipeline" and "patent expirations" insufficient). Even an express statement by a pharmaceutical manufacturer that a drug submitted for FDA approval "would be one of the main products replacing the loss of revenues from other major drugs" coming off patent is insufficient to create an inference of *scienter*. Astrazeneca, 2008 WL 2332325, at *7.

B. Plaintiffs Fail To Allege Extreme Recklessness

In the absence of a well-pled, apparent motive, "the strength of the circumstantial allegations [of conscious misbehavior or recklessness] must be correspondingly greater." Kalnit, 264 F. 3d at 142 (quoting Beck v. Mfrs. Hanover Trust Co., 820 F. 2d 46, 50 (2d Cir. 1987) (quotation marks omitted)). Here, Plaintiffs' remaining allegations of *scienter* rely primarily on three subparagraphs, repeated verbatim throughout the complaint, and taken from various slides

[22] Plaintiffs allege, for example, that Defendants were motivated by fraud to develop a blockbuster because sanofi sold its rights to the drug Exubera (an inhaled human insulin) to Pfizer for $1.3 billion during the class period. Cplt. ¶ 20. But if sanofi were so in need of a new drug that it had to commit fraud, it could have simply chosen not to sell Exubera.

presented by the FDA staff at the June 13, 2007, FDA advisory committee, the last day of the class period. None of them show that defendants had the requisite *scienter* during the class period, or ever. Plaintiffs allege that:

> (a) Prior to and during the Class Period, defendants were in possession of the results of the RIO Studies, which showed a causal link between the use of rimonabant and depression. In fact, out of 1,253 [should be "1,235"] psychiatric adverse events reported, which included various degrees of severity of depression, 1082 (88%) of them were suffered by patients who did not have a baseline history of mood disorders. See Cplt. 76(a), 81(a), 97(a), 107(a), 116(a), 123 (a); cf. Ex. LL at 41 (Egan presentation).
>
> (b) Prior to and during the Class Period, defendants were in possession of the efficacy and safety results of at least 12 rimonabant clinical studies, including the RIO Studies, which showed a causal link between rimonabant and suicidal ideation. In fact, the studies revealed 50 cases of suicidal ideation were associated with use of rimonabant, while only 14 were associated with placebo. See Cplt. ¶¶ 76(b), 81(b), 97(b), 107(b), 116(b), 123(b); cf. Ex. LL at 46 (Egan presentation).
>
> (c) During the RIO Studies, withdrawal rates for the RIO Studies ranged from 32% to 49% for the first year and 23% to 58% for the second year. Defendants failed to implement systematic follow-up procedures with patients who withdrew as a result of suffering an adverse psychiatric event, or with those patients that were excluded from the study by Sanofi because they went on a regimen of anti-depressants while a study was ongoing. As a result, defendants were unable to determine how long patients remained depressed and whether the severity of depression increased or decreased after withdrawal or exclusion from the study. See Cplt. ¶¶ 76(c), 81(c), 97(c), 107(c), 116(c), 123(c); cf. Ex. LL at 6 (Egan presentation).

Plaintiffs do not "identify any reports or statements … that would have demonstrated the falsity of the allegedly misleading statements." Teamsters Local 445, slip op. at 13-14. To the contrary, the underlying facts alleged in each of these subparagraphs either were publicly and accurately disclosed, or are not alleged to have been known at the time of any allegedly fraudulent statement. In fact, that the results of the RIO Studies were published, and that sanofi accurately described those results, itself negates *scienter*. See, e.g., Borochoff, 2008 WL 2073421, at *8 (fact that defendant disclosed its studies to FDA and made them publicly

available "rebuts any intent to defraud by concealing information"); In re GeoPharma, Inc. Sec. Litig., 399 F. Supp. 2d 432, 452 (S.D.N.Y. 2005) (contradictory information must be non-public).

Sanofi disclosed the facts (as alleged in (a)) that psychiatric adverse events were experienced by patients in the RIO Studies, as well as the baseline and treated HAD scores (which includes depressed mood disorder and depression) of the patient population. See, e.g., Ex. C at 772, Table 4 (adverse events including depressed mood defined to include "depression, major depression, depressed mood, and depressive symptoms" disclosed). Sanofi also disclosed (as alleged in (c)) that withdrawal rates for the RIO Studies ranged from 32% to 49% for the first year and 23% to 58% for the second year,[23] and that depression was among the "most frequent adverse events resulting in discontinuation," occurring, for example, in 2.9% of those patients taking 20 mg rimonabant who discontinued from the RIO-Lipids study. Ex. B at 2130-31. See also Ex. D at 1668, Table 4 (3% of 20 mg patients discontinued from RIO-Diabetes due to "depressed mood disorders"); Ex. A at 1395, Table 7 (3.7% of 20 mg patients discontinued from RIO-Europe due to "depressed mood disorders"); Ex. C at 772, Table 4 (2.2% of 20 mg patients discontinued from RIO-North America due to "depressed mood").[24]

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[23] Three of the published RIO studies contain clear, easy-to-follow flowcharts showing how many patients were screened for each trial, how many entered each trial, how many received placebo, or 5 mg or 20 mg of rimonabant, and how many in each group subsequently withdrew, and for what reason. See Ex. C at 762; Ex. A at 1390; Ex. D at 1662. The RIO-Lipids study (a 12-month study) contains the same dropout information in a table, and the first sentence of the "Results" section states that the dropout rate was about 40 percent. See Ex. B at 2124, 2121. As to the significance of these rates, the FDA staff itself noted that "high attrition rates are not unique to rimonabant. They tend to occur with all weight-loss drugs and with some other drugs as well." Ex. HH at 254.

[24] Plaintiffs also contend that sanofi performed insufficient patient follow-up procedures, such that sanofi was unable to determine the full extent of depression associated with rimonabant. See Cplt. ¶¶ 76(c), 81(c), 97(c), 107(c), 116(c), 123(c). This allegation seems to undermine Plaintiffs' (incorrect and unsupported) contention that a causal relationship was apparent from the data sanofi did gather. In any event, the dropout rates were fully disclosed. The RIO studies clearly discuss limitations caused by high discontinuation rates (though typical in obesity studies). RIO-North America states that the "low retention rates of only about 50% in all treatment groups, while consistent with previous studies in overweight or obese patients, present a major challenge in data analysis and interpretation," and that "it must be acknowledged that the trial was limited by a high drop-out rate and that

Although Plaintiffs claim that "the studies revealed 50 cases of suicidal ideation were associated with use of rimonabant, while only 14 were associated with placebo,"[25] the Amended Complaint does not allege, and indeed refutes, that such information was available at the time of sanofi's statements.[26] The advisory committee proceedings, on which plaintiffs rely, make clear that such data only became available later as a result of retrospective analysis done by Dr. Posner based on the trials that had already been performed.[27]

Plaintiffs also suggest that the approvable letter sanofi received in February 2006 establishes scienter. See Cplt. ¶¶ 29, 61, 97(d), 107(d), 116(d), 123(d). However, the approvable letter itself demonstrates only that the FDA had unresolved questions about "associations between rimonabant and increased frequencies of psychiatric adverse events," Cplt. ¶ 61, not that it reached conclusions. Indeed, the FDA concluded the NDA was "approvable," see Ex. M, and that sanofi's subsequent resubmission of its NDA was "complete." Cplt. ¶ 112; Ex. Z.

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long-term effects of the drug require further study." Ex. C at 774. RIO-Diabetes states that there are two limitations to the study, one of which is that "the retention rate of about 66% in all treatment groups might be considered as rather low." Ex. D at 1670. Furthermore, RIO-Diabetes specifically disclosed that "in this trial, as in other RIO-trials, patients with severe psychiatric disorders or receiving antidepressants were excluded, so the safety of rimonabant in such individuals remains to be determined." Id. (emphasis added). The RIO-Lipids study included the drop-out rate in the first sentence of the results section, noting that "about 40% of the patients in each of the three treatment groups dropped out during the 12-month study." Ex. B at 2125. Both the issue of patient drop-outs and the potential need for further study were fully disclosed to investors.

[25] Plaintiffs added the figures presented by the FDA for the 5 mg and 20 mg doses of rimonabant to make this claim. See Ex. LL at 46 (Egan presentation).

[26] Plaintiffs allege that it was "the supplemental data from the RIO Studies and other clinical trials completed by Sanofi . . . [that] revealed 50 cases of suicidal ideation in rimonabant treatment groups compared to 14 in placebo," Cplt. ¶ 24 (emphasis added), and that such information was collected only after the Approvable Letter and after the bulk of the statements at issue. The RIO Studies each disclose on their face that they used a methodology for assessing depression-related events—the HAD score system—that does not measure suicidality or suicidal ideation, a subset of suicidality. See supra n.17. Sanofi correctly stated, however, that no new clinical studies had been requested by the FDA. See Cplt. ¶ 103.

[27] The presenting member of the FDA staff explained that, after the submission of the original rimonabant NDA, "the [FDA] also requested that Sanofi obtain a formal assessment of suicidality from Dr. Kelly Posner's group at Columbia University." Ex. HH at 282-83 (AC Tr.).

Distilled to their essence, Plaintiffs' allegations of *scienter* consist simply of the conclusory assertion that the results of clinical studies unambiguously showed "a causal link between rimonabant and suicidal ideation." Cplt. ¶ 35. The sole basis for this conclusion appears to be that the FDA staff took the position at the advisory committee meeting on June 13, 2007, that the "meta-analysis indicates an increased risk for suicidality, specifically suicidal ideation, in subjects taking rimonabant 20 mg vs. placebo." Ex. HH at 292 (AC Tr.) The meta-analysis was performed using Dr. Posner's novel C-CASA methodology, as the FDA presenter noted. See id. at 283. Earlier in the advisory committee testimony, Dr. Posner had noted the difficulty inherent in developing a methodology to apply to studies that had not been designed to assess for suicidality, adding that the newer, prospective version of her methodology was often being recommended by the FDA for use in ongoing or future studies. Id. at 29.[28]

More importantly, sanofi did not agree with the FDA staff. It opined that, in performing its meta-analysis with respect to one study that was not placebo-controlled, the "FDA used the 5 mg as the placebo control, which," sanofi stated, "we do not feel is appropriate for several reasons." Id. at 115. Instead, sanofi "took an approach of using placebo-controlled studies only where a placebo is always a placebo," id., and on the basis of that analysis, expressed the contrary view that "a causal relationship has not been established between suicidality and the use of rimonabant." Id. at 122. Plaintiffs fail to allege that this position was

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[28] Plaintiffs offer only general allegations of access to data by corporate officers. See Cplt. ¶¶ 55, 57. They also point to the statement that "we have looked at the database fairly closely and no concerns have arisen . . . [W]e're well along in amassing the entire [safety] database." Cplt. 55; see also Cplt. ¶¶ 53-60. However, absent an allegation that the clinical trial database contained specific information about suicidality and that the defendants made statements that contradicted information actually known to them, these allegations are insufficient. See, e.g., In re Bristol-Myers Squibb Sec. Litig., 312 F. Supp. 2d 549, 562 (S.D.N.Y. 2004). See also Dynex, 2008 WL 2521676, *5; Novak, 216 F.3d at 309 (2d Cir. 2000) ("[c]orporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonably available to them") (emphasis added, citing Denny v. Barber, 576 F.2d 465, 469 (2d Cir. 1978)). Further, if as Plaintiffs suggest causality were apparent from the published RIO Studies, then the investing public and the market were fully aware of that fact. Plaintiffs themselves

unreasonable or feigned, or importantly, that any defendant ever reached during the class period conclusions similar to those expressed by the FDA staff at the end of the class period.

In In re Carter-Wallace, Inc., Securities Litigation, 220 F.3d 36, 38 (2d Cir. 2000), the Second Circuit rejected allegations of "conscious misbehavior" that were "based solely on the allegation that [a drug manufacturer] touted [a drug's] safety while it was receiving adverse medical reports." Id. at 40. The Carter-Wallace plaintiffs (like these Plaintiffs) simply alleged that the "adverse effects . . . were extremely serious and the number of incidents was . . . statistically unacceptable[.]" Id. The Second Circuit pointed to the difficulty of discerning causal relationships between a drug and reported adverse reports, id. at 40-41, and held that "actual awareness of adverse reports while touting [the drug's] safety does not, on its own, constitute 'strong circumstantial evidence of conscious misbehavior or recklessness.'" Id.

Following Carter-Wallace, the Court in In re Astrazeneca Securities Litigation dismissed an action similar in all respects to this one. There, the drug sponsor, AstraZeneca, submitted an NDA for an anti-coagulant that it claimed was "at least as effective as the gold standard" and would "dominate the ... market." Astrazeneca, 2008 WL 2332325, at *3. Prior to the FDA's decision on the drug, the sponsor claimed that liver enzyme elevations that were reflected in studies "were typically transient." Id. at *4. It did not disclose that the FDA had asked it to provide additional data on safety, including a "Risk Management Program." Id. at *9. Ultimately, the FDA convened an advisory committee meeting, at which the FDA staff opined that—contrary to the sponsor's conclusions—there was a substantial risk of severe or fatal liver injury. Id. at *7. The advisory committee voted against approval and the NDA was subsequently withdrawn. Id. at *9.

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allege that "the safety data associated with the RIO Studies was grim." Cplt. ¶ 24. Whether the safety data was "grim" or not is a matter of opinion, but the study results certainly were publicly disclosed.

The Court held that these circumstances did not establish *scienter* and dismissed the complaint. It ruled:

> In the long recital of information about [the drug Exanta] given to the public, there is nothing whatever to indicate that the statements made did not reflect the honest belief of the authors. There is no allegation of any "red flag" or anything else to indicate that defendants knew that the statements were false or misleading or that defendants were recklessly issuing false or misleading information to the public. Nothing appears in the complaint showing that there was a consensus of the management that the risks of Exanta made the drug unlikely to be approved. Further, other facts, such as the approval of Exanta in Europe for some uses, made it not unreasonable for defendants to believe in their product.
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> * * *
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> As to the FDA Briefing Document . . . , it is the view of the Court that this document does not in fact have the significance attributed to it by plaintiffs. It does not demonstrate that there were certain dangers, known all along to defendants, which would prevent the approval and marketing of Exanta. . . . As of the time when the FDA Advisory Committee met [ ] the [sponsor] had its side of the case and the FDA staff had its side. The FDA staff view prevailed before the Advisory Committee. This does not mean that [the sponsor] was not conscientious in advocating the drug [ ] before the FDA, nor does it mean that the information issued publicly over the course of more than a year was dishonest or recklessly disseminated.

Id. at *17 (citing Kalnit, 264 F.3d at 142; Bayer, 2004 WL 2190357, at *14). The same conclusion follows here, and this action should be dismissed. See also Nathenson v. Zonagen, 267 F.3d 400, 420 (5th Cir. 2001) ("[m]edical researchers may well differ with respect to what constitutes acceptable testing procedures, as well as how best to interpret data garnered under various protocols") (quoting Padnes, 1996 WL 539711, at *5); Oran v. Stafford, 226 F.3d 275, 294 (3d Cir. 2000); In re Alliance Pharm. Sec. Litig., 279 F. Supp. 2d 171, 189 (S.D.N.Y. 2003); Pfizer, 2008 WL 540120, at *5 ("plaintiffs' allegations do not support an inference that defendants actually drew a negative conclusion from the inconclusive evidence"); In re Medimmune Inc. Sec. Litig., 873 F. Supp. 953, 966 (D. Md. 1995); In re Biogen Sec., 179 F.R.D. 25, 38 (D. Mass. 1997); Borochoff, 2008 WL 2073421, at *9.

CONCLUSION

The Amended Complaint must be dismissed with prejudice.

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